# Optiscan

The *new standard* in digital pathology and precision surgery.

Optiscan Imaging Ltd. (ASX:OIL)

Annual General Meeting
21 November 2024

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### Chairman's Address



Mr Robert Cooke
Non-Executive Chairman



# Optiscan Board: Experienced Leadership



Robert Cooke Board Chair

- 40-year career in health industry
- Executive leadership roles in healthcare companies in Australia, Asia and UK



Camile Farah CEO & MD

- 25 years' experience in healthcare leadership, medical research, medtech R&D
- Dual trained physician and pathologist with international reputation and network



Sean Gardiner Non-Executive Director

- Managing Director of Clermont Capital, Singapore
- 20 years' experience in equity research, with senior roles at Morgan Stanley



Karen Borg Non-Executive Director

- Medtech leader who has held senior executive roles in private and public sectors
- Formerly with Johnson & Johnson USA, currently with SomnoMed



Ron Song Non-Executive Director

- Track record of developing highly profitable ventures with a network of global contacts
- Formerly managed BMW & Audi dealerships in APAC

### Chairman's Address

#### **CHAIRMAN'S AGM ADDRESS**

Optiscan Imaging Limited (ASX: OIL) (the 'Company' or 'Optiscan') provides the following Chairman's address which will be made to the Annual General Meeting of shareholders 21 November 2024.

At the beginning of the FY24 financial year, the Company raised \$16,698,816 through a partially underwritten renounceable entitlement offer to fund its strategic portfolio expansion.

The Company put the funds to immediate use and quickly unveiled its new ground-breaking microscopic medical imaging device for precision surgery, the InVue®. Clinical studies for the first surgical indication in breast cancer surgery are expected to commence in Melbourne and the US over the coming months, to collect suitable data for an FDA regulatory submission.

The Company continued its discussions and preparation for its FDA De Novo application for its devices which will focus on surgical applications for both InVue® and InVivage®. Good progress has been made in relation to the extensive documentation required for these submissions and for planning of clinical trials here and aboard.

During the year, the Company signed a collaborative Know How agreement with the prestigious Mayo Clinic, the #1 US ranked hospital system, to co-develop an endomicroscopic imaging device for minimally invasive robotic-assisted surgery. This collaboration is a massive endorsement of the Company and its technology. We look forward to exploring other opportunities with the Mayo Clinic in due course.

The Company continued to work with our partner, Prolucid Technologies to develop telepathology cloud infrastructure, with the goal to achieve Minimal Viable Product by June 2025. At the same time, the Company made progress with development of its Artificial Intelligence (AI) algorithms which will focus on oral, breast and GI imaging in the first instance.

The Company was awarded a \$3 million CRC-P project grant from the Federal Government to develop its next generation flexible GI endomicroscope in collaboration with University Medical Center Mainz Germany, Monash University and D+I. This project will see significant advancements made to the Company's core technology which will ultimately secure wider clinical utility for its various devices.

Concurrently with a focus on the US market, the Company continues to deliver high quality product to Carl Zeiss Meditec with all deliveries occurring ahead of schedule. In parallel, the Company has delivered several research devices through its China-based distributors, while focussing efforts on increasing its sales pipeline in the US and EU.

The Company continues its transformation journey from an OEM to a private label manufacturer, de-risking the business with a diversified product portfolio of hardware and software, and increasing its capabilities across clinical, regulatory, sales and marketing with new staff appointments. Work continues on delivering a pathology laboratory device, and another suitable for the lucrative veterinary medicine market.

The Company is well positioned to capitalise on the significant milestones met during the FY24 year, with more positive future developments in progress over the coming year. We look forward to updating the market on these developments in coming months.

I would like to thank our executive team and employees for their significant contributions during the year as the Company continues to develop into a global leader in its field.

On behalf of the Board, I would like to thank our shareholders for their continued and much valued support over the past year.



# Managing Director's Report



**Dr Camile Farah CEO & Managing Director** 



# Acknowledgement of Country

I begin today by acknowledging the Traditional Owners of the land on which we meet, the Wurundjeri and the Boon Wurrung people of the Kulin Nation, and pay my respects to their Elders past, present and emerging.





### Optiscan at a Glance

#### A global medical technology company leading the transformation of digital pathology and precision surgery



**ASX: OIL** 

1997



Melbourne

Headquarters



\$137m

Market Cap



**Patent** 

Protected



Technology



Proven



Validated

**Products** 



Team

Agile Office & Plant

2,350 m<sup>2</sup>



QMS Certification



Commercial Hub

Minnesota

#### **Highest-Resolution Sub-Micron Live Microscopic Imaging Platform**

- Fluorescence-based confocal laser endomicroscopy
- Single optical fibre distal end scanning suitable for high precision clinical interventions
- Fluorescence intensity creates real-time digital microscopic images 0
- Moving lenses create variable focal planes for **imaging depth** up to 400 μm
- Images are up to 1000x real magnification with subcellular level resolution of 0.55 µm





# Key Achievements - Significant Milestones FY24

#### Key Achievements FY24

| Capital                   | \$16.7m Entitlement Issue Successful completion of a \$16.7m capital raise to develop new clinical devices and product innovations   | July 2023 |
|---------------------------|--|-----------|
| Product<br>Development    | Telepathology Milestone Project with Prolucid passes proof of concept ahead of schedule  | Aug 2023  |
| Clinical                  | Breast Study Milestone Optiscan technology correlates with histology in intraoperative assessment study at the Royal Melbourne Hospital, Frances Perry & Epworth Hospitals   | Sept 2023 |
| Commercialisation         | Key sales appointments strengthen AU and US operations Brendan Fafiani appointed COO, Shayra Leon and Tim Rowe appointed Business Development Managers for North America   | Oct 2023  |
| Non-Dilutive<br>Funding   | Optiscan receives \$3 million CRC-P industry grant Funding to support development of Optiscan's second-generation flexible gastrointestinal endomicroscope   | Feb 2024  |
| Clinical &<br>Regulatory  | Optiscan establishes US Regional Office in Minnesota and appoints US clinical & regulatory managers  The Company takes up premises at the Minnesota BioBusiness Center adjacent to the Mayo Clinic in Rochester to drive clinical and regulatory submissions | Apr 2024  |
| R&D and Commercialisation | Optiscan Signs Know-How Agreement with Mayo Clinic Optiscan and Mayo Clinic will co-develop technology for use in minimally invasive robotic-assisted surgery  | May 2024  |













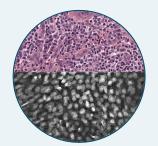


# Key Achievements - Significant Milestones FY24

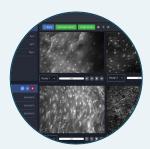
#### Key Achievements FY24

| Product<br>Development | Optiscan Reveals InVue® Device for Precision Surgery InVue® expands Optiscan's product portfolio into the surgical application market   | Jun 2024 |
|------------------------|---|----------|
| Capital<br>Market      | Optiscan undertakes 2024 Investor Roadshow Company highlights its recent achievements and development strategy milestones   | Jul 2024 |
| Clinical               | Optiscan Receives Ethical Clearance for Breast Cancer Study  The study will assess Optiscan's recently unveiled InVue® precision surgery imaging platform in breast cancer imaging in vivo                                | Jul 2024 |
| Product<br>Development | Major Development Milestone Delivered in Optiscan's Telepathology Platform Optiscan completes beta phase of its cloud-based telepathology platform in collaboration with partner Prolucid Technologies                    | Jul 2024 |
| Clinical               | Optiscan Signs MOU with University of Minnesota College of Veterinary Medicine The agreement combines Optiscan's technology with the University of Minnesota's research capabilities, veterinary facilities and expertise | Aug 2024 |
| R&D                    | Optiscan Signs Agreement with Monash to Progress Flexible GI Scope Optiscan will collaborate with Monash University to develop the project's next-gen AI technology   | Nov 2024 |
| Clinical               | Optiscan Signs Collaborative Research Agreement with Minnesota Vet College The veterinary medicine segment represents a significant global market opportunity   | Nov 2024 |















# Strategic Partnerships & Collaborations

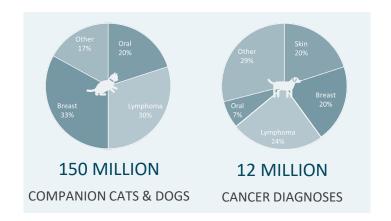
**Robotics** 





Veterinary





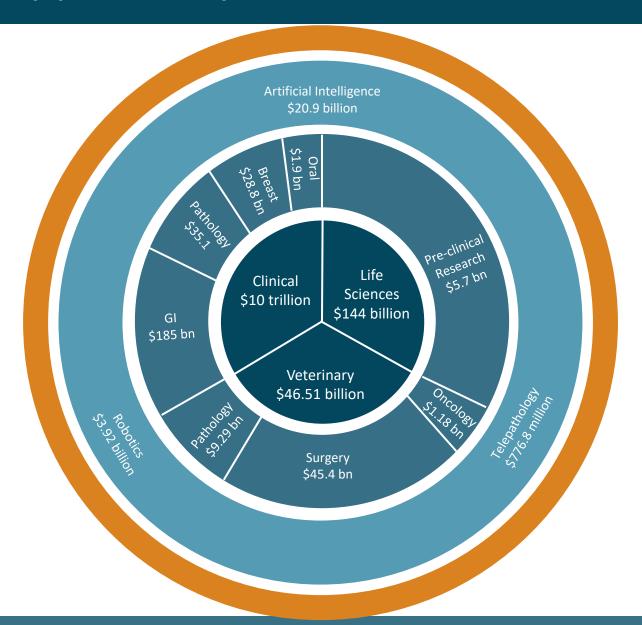
Gastroenterology







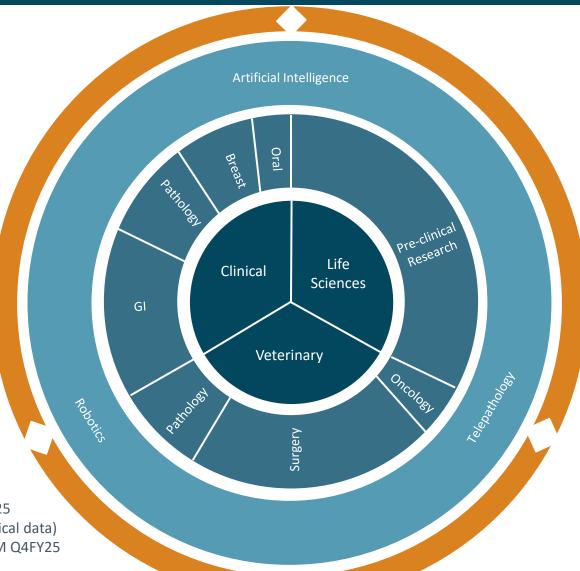
### The Optiscan Opportunity





### Progress to date

- InVue® reveal (Surgery)
- InVivage® compliance update (Oral)
- Flexible scope development (GI)
- Mayo Clinic Agreement (robotics)
- Pathology laboratory device reveal Q3FY25
- Telepathology platform MVP Q4FY25
- Al development in progress (Prolucid and Monash)



- Sales & marketing appointments in AU and US
- Outsourced business development in EU
- Renewed distributor agreements in APAC
- ViewnVivo® expanding sales pipeline in US, China, EU
- Extension into Veterinary research market
- Actively pursuing pharma sales opportunities

Veterinary device readiness Q4FY25

- Uni of Minnesota Agreement (clinical data)
- Regulatory submission to FDA CVM Q4FY25

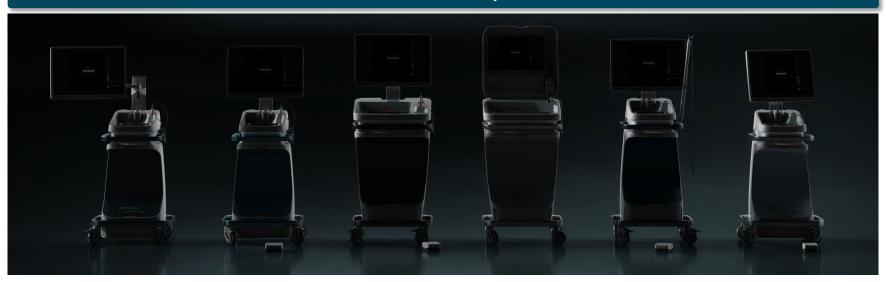


### Expanding Product Range - Clinical & Life Sciences



### Diversified Hardware & Software Portfolio

#### **Clinical Device Family Vision**





#### **Full Suite of Digital Health Assets**



Live Streaming
Telepathology Software &
Remote Diagnostics



Al Based Software as a Medical Device



Biopsy Channel Compatible Devices



Integration with Robotics
Systems

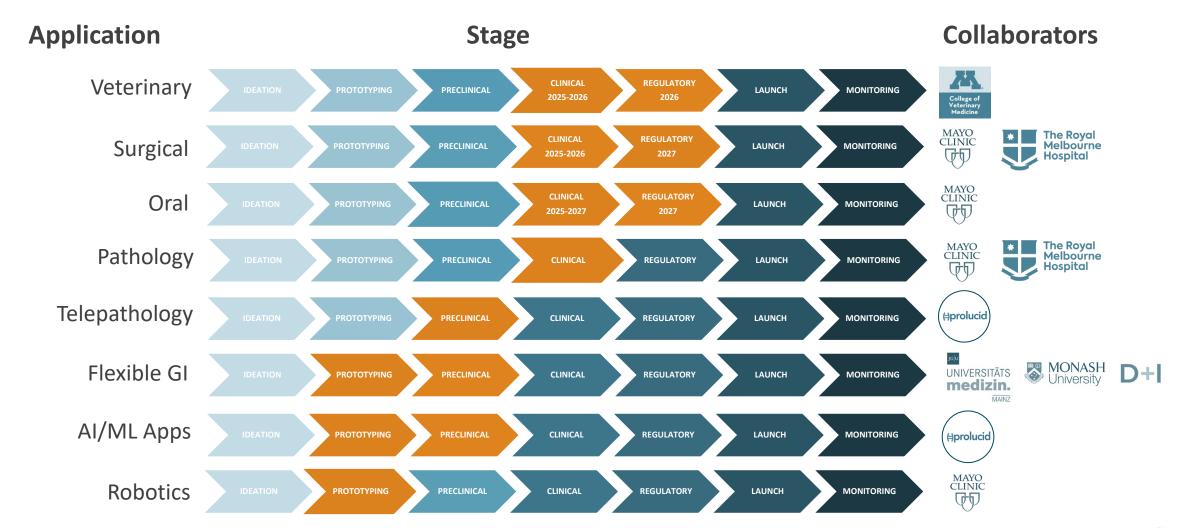


Image-guided Molecular Surgery

Horizontally and Vertically integrated product range with large addressable markets

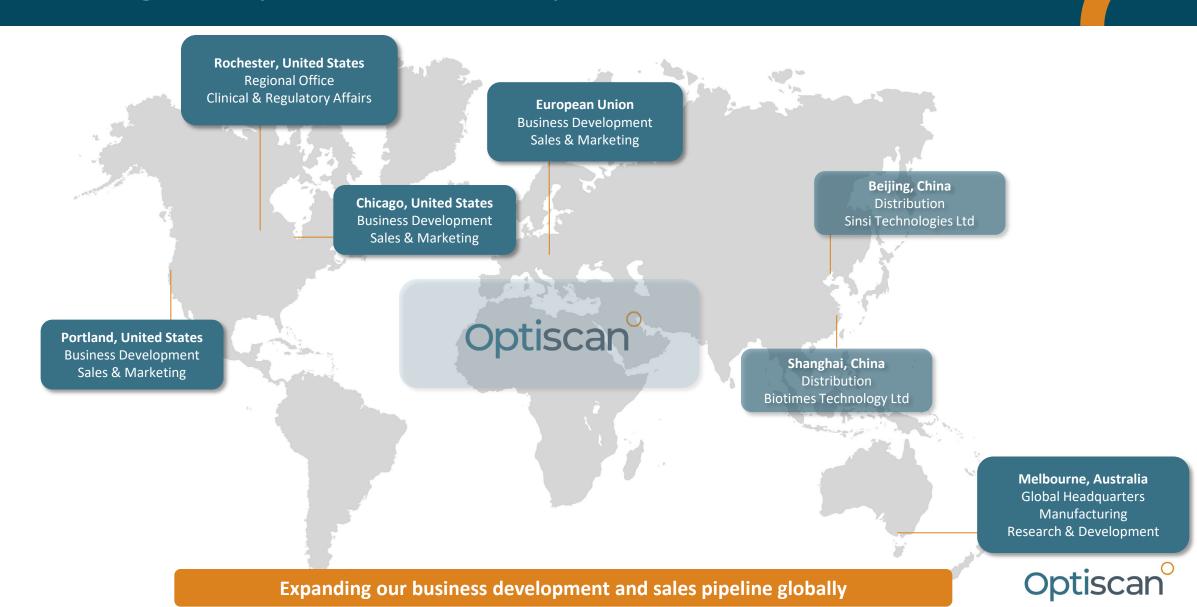


# Product Development Pipeline - Multiple Shots at Goal





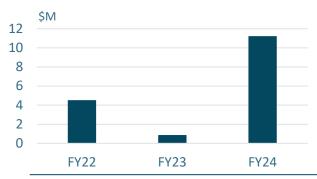
# **Growing Footprint & Sales Pipeline**



### FY24 Financial Highlights

#### Strong capital position and increased income.





#### \$16.7m capital raised to advance multiple R&D projects

- Balance sheet in FY24 remained strong with a cash and term deposit balance of \$11.2m
- Balance as of Sep24 remains strong at \$9.1m
- Significant advancements in R&D have been made to develop new clinical devices and product innovations

#### **Revenue and Other Income**



#### FY24 Total Income (Revenue & Other Income) up ~33% on FY23 to \$3.53m

#### Other income

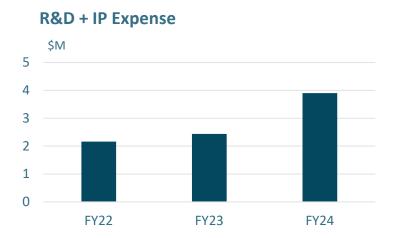
- Non-dilutive funding has increased by more than double to \$2.4m with the successful CRC-P grant funding and higher R&D tax incentive income
- Other income projected to increase, in line with higher R&D activities

#### Revenue from sale of products

- Revenue from sales to CZM declined by 31% to \$1.1m highlighting importance of pursuing multi-pronged private label strategy
- Key US staff hires in FY24 has increased sales pipeline value for FY25 Optis

# FY24 Financial Highlights

#### Advancing R&D projects, achieving strategic milestones.



#### Increased capital allocation to R&D has yielded success

- Reveal of ground-breaking new microscopic medical imaging device,
   InVue® for precision surgery
- Collaboration with Mayo Clinic has begun to develop an imaging system for use in robotic-assisted surgery
- Flexible GI scope, pathology laboratory device, and veterinary medicine device being developed in parallel on track for delivery
- Collaboration with Uni of Minnesota College of Veterinary Medicine will accelerate collection of clinical data for adoption







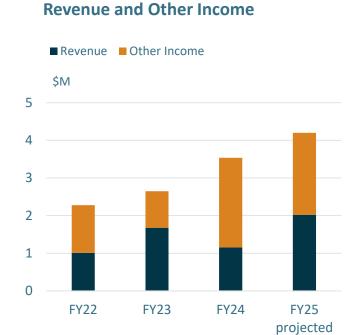






### FY25 Market Update

#### Projected increased revenue from sales and other income.



# FY25 Total Income (Revenue & Other Income) projected to increase up to 20%, approximately \$4.2m from FY24

#### Revenue from sale of products

- FY25 revenue from ViewnVivo® sales projected to increase by nearly double from FY24
- Increased sales from growing ViewnVivo® pipeline projected for FY26, due to long 12 to 18 months sales cycle
- FY25 sales from to CZM projected to be in line with FY24 outcome

#### Other income

- Non-dilutive funding from CRC-P grant expected to be received over the next 2 years with a total value of approximately \$2m
- R&D tax incentive income projected to increase over coming years as increased investment is placed in R&D to advance multiple projects locally and overseas



# Increasing Sales Pipeline for ViewnVivo® in FY25

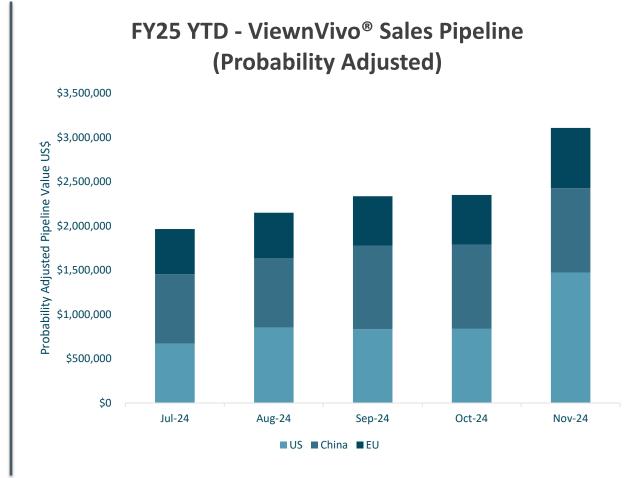
**Strong Pipeline Growth:** Significant progress driven by targeted engagements.

**Early Success in the US:** Growing interest and opportunities from key institutions.

**Consistent Performance in China:** Major university sale highlights ongoing demand, with more expected.

**Global Momentum:** Expanding recognition across Europe and other regions.

**New Opportunities:** Emerging adjacent markets offering growth potential.





### FY25 Market Updates

#### Optiscan Imaging Ltd



#### **Market Activity**

- Optiscan has undertaken an investor roadshow and presented at multiple investor conferences over the last 6 months with increased investor and public relations engagement.
- Share price performance has been positive over the past year, reaching a 3-year high of \$0.26, and stabilizing at 110% that of January 2024.
- Optiscan will continue to actively engage with the market as the company progresses with its multiple R&D projects, clinical trial launches, and preparations for regulatory submissions.



### Positioned for Growth

**Phase 1: Core foundation** 

- Develop core platform and initial product offering
- Patented technology development
- Prove legitimacy of the product
- OEM product provider

#### **Phase 2: Strategic transformation**

- Strategic focus
- Optimised operations
- Investment in growth opportunities and markets
- Expanding product portfolio
- Technology commercialization
- Cultivate strategic partnerships
- Establish US operations

2022 - 2026

#### **Phase 3: Strategic growth**

- Digital health solutions leader
- Full suite of digital health products
- Clinical devices for Breast, GI, Vet, Robotics
- Pure-play digital medical device company
- Significant market share in digital health sector

2027 +

1994 - 2021



### **Optiscan Investment Opportunity**

#### **Value Proposition**

Revolutionary Patent-Protected Technology Versatility of Platform & Global Applications

**Limitless Growth Potential** 

Diversified Hardware & Software Offerings









#### **Market Differentiators & Investment Thesis**

High Barrier To Entry
+ Product
Differentiation



Competitive
Advantage In Large
Addressable
Markets



Scalability +
Diversification



Revenue + Market
Capitalization
Expansion



Recurring Revenue Streams + End To End Control



Massive Exit
Potential





### Contact Us



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www.optiscan.com



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Breast Cancer - \$28.8 billion and CAGR 9.9% - https://www.precedenceresearch.com/breast-cancer-market

GI Market - \$185.4 billion and CAGR of 2.75% - https://www.statista.com/outlook/hmo/hospitals/inpatient-care/gastroenterology/worldwide

 $Clinical\ Pathology-\$35.1\ and\ CAGR\ 7\%-https://www.marketsandmarkets.com/Market-Reports/anatomic-pathology-market-137323145.html$ 

Veterinary Medicine - https://www.grandviewresearch.com/industry-analysis/veterinary-medicine-market

Veterinary Pathology - \$9.29 billion and CAGR of 10% - https://www.grandviewresearch.com/industry-analysis/veterinary-diagnostics-market

Veterinary Surgery - \$45.4 and CAGR 7% - https://www.marketsandmarkets.com/Market-Reports/veterinary-surgical-procedures-market-192772026.html

Veterinary Oncology - \$1.18 billion and CAGR 11.29% - https://www.grandviewresearch.com/industry-analysis/veterinary-oncology-market

Life Sciences - https://www.grandviewresearch.com/industry-analysis/life-science-tools-market

Global AI in Healthcare - https://www.marketsandmarkets.com/Market-Reports/artificial-intelligence-healthcare-market-54679303.html

Robotic Surgery - \$3.92 billion - https://www.grandviewresearch.com/industry-analysis/surgical-robot-market

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